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### Evaluation of treatments is threatened by EC directive

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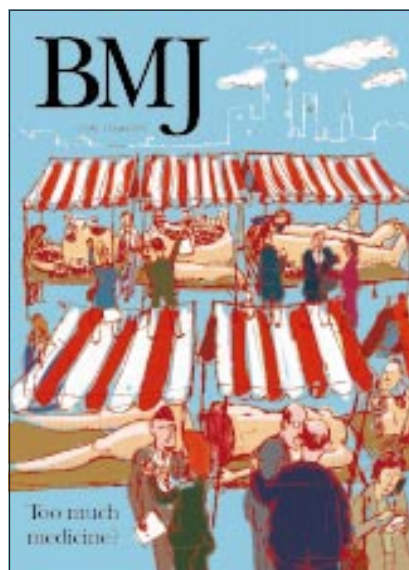
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## The pharmaceutical industry and disease mongering



### The industry works to develop drugs, not diseases

EDITOR—It is true that the pharmaceutical industry, with others, is involved in sponsoring the definition of diseases, as suggested by Moynihan et al.<sup>1</sup> Both the pharmaceutical industry and regulatory authorities that license new medicines need to develop closely defined definitions so that the safety and efficacy of new medicines can be properly measured.

More medicalisation is in fact needed, as indicated by Ebrahim and Bonaccorso and Sturchio.<sup>2,3</sup> The rise of guideline led care around the Western world shows that far too many serious diseases are underdiagnosed and undertreated. Failure to put evidence based medicine into practice is quite legitimately addressed by the pharmaceutical industry. Examples include the underuse of statins in the United Kingdom, the delay in the uptake of thrombolysis during the 1980s, and reliance on old psychotropic drugs when newer agents have a much more favourable profile of side effects.

Of course, disease awareness campaigns are likely to expand the market for drugs for a given disease, but the market will expand for competitors' products as well as those of the sponsoring company. However, the real value of disease awareness campaigns is exactly what it says: making consumers aware that treatment may be available for

their condition. Not infrequently, major disease is detected as a result of a patient seeking medical advice after contact with a disease awareness campaign.

Moynihan et al imply that preventive medicine is threatening the viability of publicly funded healthcare systems. Yet clearly, it is far better to prevent disease than to treat it when it is established. The benefits of stopping smoking, treating hypertension, reducing raised blood lipid concentrations, etc, are all well established but could not be done without the help of the pharmaceutical industry.

In choosing the diseases that Moynihan et al detail as sponsored by the pharmaceutical industry, it is unfortunate that the Australian experience has been highlighted. In Europe patients cannot be targeted with promotional material and such material for health professionals in the United Kingdom has to comply with the code of practice of the Association of the British Pharmaceutical Industry. Moynihan et al imply that osteoporosis has been effectively sponsored by the pharmaceutical industry. However, far too many people who fall and develop a fracture are not considered for treatment of osteoporosis.

In conclusion, the pharmaceutical industry is not inventing disease but rather working hard to develop new, innovative drugs for the overall benefit of humankind.

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2 Ebrahim S. The medicalisation of old age. *BMJ* 2002;324:861-3. (13 April)

3 Bonaccorso SN, Sturchio JL. Direct to consumer advertising is medicalising normal human experience: against. *BMJ* 2002;324:910-1. (13 April)

### Article was insulting to people with osteoporosis

EDITOR—I was surprised that the *BMJ* published the unbalanced and poorly researched article of Moynihan in which osteoporosis was dismissed as a "risk masquerading as a disease" and compared in severity to baldness.<sup>1</sup>

This article was insulting to all men and women who have excruciating pain and severe loss of quality of life from osteoporosis.

The article wrongly stated that the risk of fracture for most people is low: in fact 1 in 3 women and 1 in 12 men over 50 are destined to have at least one fracture.

The article also implied that population screening is advocated for osteoporosis: it is not. Neither the National Osteoporosis Society nor the International Osteoporosis Foundation advocates screening all men and women. However they do advocate that those in high risk groups should seek their doctor's advice and be assessed. These same groups are advocated in the Royal College of Physicians' report on osteoporosis and in section six of the government's national service framework for older people.<sup>2,3</sup>

Moynihan et al also argued that we should not ask pharmaceutical companies to put money into campaigns to provide information about the disease. Why not?

All profit making companies should be expected to put money back into helping patients, provided that they do not tell patient organisations what to say. As a national society, we follow strict guidelines in our dealings with pharmaceutical companies, but we expect them to support some of our work and the enlightened ones do. A modest percentage of our income comes from pharmaceutical companies, which is useful, but we are not dependent on it.

A more appropriate target would be health authorities that currently provide no

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service for patients with or at high risk of osteoporosis, although good evidence shows that it would be cost effective to treat to prevent the high cost of further fractures.

The National Osteoporosis Society in the United Kingdom and our sister societies in other countries are certainly not "attempting to persuade millions of healthy women that they are sick," but we do have a duty to inform people about the seriousness of osteoporosis. We must also provide information about diet, exercise, and other lifestyle measures that can be taken from the cradle to extreme old age to help prevent this devastating disease.

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- 1 Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering [with commentary by P C Göttsche]. *BMJ* 2002;324:886-91. (13 April.)
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### Drugs can be good for you too

EDITOR—Moynihan et al tell us that the marketing departments of pharmaceutical companies market pharmaceutical products.<sup>1</sup> Shock horror. Well, tobacco companies market cigarettes, McDonald's markets junk foods, and motor car manufacturers market cars. The difference is that pharmaceutical products can be good for your health.

To pick one of the examples given in the paper: Moynihan et al would have us believe that there is something evil about raising awareness of social phobia. Social phobia is a difficult disorder to define, as there is a continuum from normal shyness to a disabling psychiatric disorder, and it is not therefore surprising that estimates of its prevalence vary wildly.<sup>2</sup> This should not detract from the fact that many people genuinely suffer from the disorder, and that those people can be helped by treatment.<sup>3</sup> Why is it wrong to help them?

Of course there is a conflict of interest when pharmaceutical companies market their products, and Moynihan et al are right to point out that prescribers should be aware of this when listening to the marketing messages. We should not assume, however, that advice about prescribing originating from pharmaceutical companies is wrong just because the company stands to gain.

Moynihan et al recommend that information provided by pharmaceutical companies should be replaced with information from unbiased sources. This is a fine idea in principle, but providing high quality information is expensive. Who is going to pay for it if not the pharmaceutical companies?

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### Authors were incorrect in their comments about Osteoporosis Australia

EDITOR—Moynihan et al raise several important issues in their article on disease mongering, so it is a pity that they followed a rule well known in journalism: "don't let the facts get in the way of a good story."

With respect to osteoporosis, they make several incorrect assertions and are selective in citing the literature. Osteoporosis Australia is not a medical foundation but an independent charity to promote the cause of patients with osteoporosis. It has received funding from industry but also from the federal and state governments. The risk test developed by the International Osteoporosis Foundation refers to women with an early menopause before age 45, not "any menopausal woman." Also, it does not state that a single risk factor is sufficient to justify bone density testing, rather that a woman should take the whole checklist to a doctor for discussion about the need for further testing.

The authors express concern that pharmaceutical companies often fund meetings "where the disease [is] being defined." Osteoporosis Australia and the National Prescribing Service convened a fracture summit in 2001 to develop an evidence based approach to the management of osteoporosis. This meeting, which included representatives of the Pharmaceutical Benefits Advisory Committee, specifically excluded any funding by the pharmaceutical industry. Its outcome concluded that there was only weak evidence to support what the authors suggest are "moderately effectively non-pharmacological strategies, such as weight bearing exercise."<sup>2</sup>

The authors are selective in their reporting relating to bone density, which is widely accepted as the best predictor of fracture risk. The article by Wilkin quoted to suggest that bone density is not an accurate predictor of individual fracture risk was also accompanied by a commentary that challenged this conclusion, but the author failed to cite this counter view.<sup>3</sup>

It seems that the authors would have people with osteoporosis be reassured that they don't have a real disease, just a risk factor—low bone mass. Much of the rest that the authors say is from "conversations with industry insiders" and numerous personal communications. This is not evidence but hearsay. The article is written in tabloid style, and perhaps a tabloid newspaper is where it should have been published. Rational debate is to be encouraged, but selective reporting by authors with agendas is inappropriate.

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### It was ever thus

EDITOR—Moynihan et al's article gave me an overwhelming sense of déjà vu.<sup>1</sup> Long before reading medicine as a mature student, I did a degree in psychology and spent several years in the late 1960s and early '70s working for a market research company that specialised in qualitative or "motivational" consumer research. Our task was to use psychoanalytical techniques to delve into the attitudes and motivations of the consumer. Our purpose was to provide companies' marketing and advertising departments with ammunition to exploit the fears, weaknesses, and desires of consumers so that they bought the companies' products.

Three examples spring to mind: women's worries about vaginal odour and hygiene were exploited in order that vaginal deodorants were sold; a new range of therapeutically useless pharmaceutical products was developed for emerging Third World markets, playing on the superstitions of the uneducated, "native" mind; and "safe," low tar cigarettes were promoted to combat the new government health warnings on cigarette packets.

I am surprised that the medical world took so long to catch on to the devious techniques at which the pharmaceutical industry excels. I have always been amazed by doctors' naivety in their uncritical acceptance of drug company sponsorship of medical education and their willingness to accept the "evidence" of drug company representatives about the wonderful properties of the latest drug.

I have been a general practitioner for 11 years, but my memory of the methods used in marketing and advertising is clear.

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### Déjà vu all over again

EDITOR—Moynihan et al's article on disease mongering by the pharmaceutical industry<sup>1</sup> reminded us of an old Bronx baseball saying, originating with Yogi Berra: "It's déjà vu all over again." 3M has for years sponsored the 3M/National Vaginitis Association ([www.vaginalinfections.com](http://www.vaginalinfections.com)). This produces a newsletter for health professionals (the *Vaginitis Report*) and materials for patients. Like the groups described by Moynihan et al, the 3M/National Vaginitis Association is ostensibly an educational resource run by health professionals.

Unfortunately, its activities include a large element of disease mongering. Mild



symptoms are offered as portents of serious disease, and doctors are encouraged to be aggressive in their attempts to diagnose and treat vaginal infections, specifically bacterial vaginosis. As luck would have it, 3M produces a drug that treats bacterial vaginosis. More recently, the 3M/National Vaginitis Association established a free telephone number to distribute a free "educational brochure" promoted by a television personality.

The association provides a further example of what Moynihan et al describe as using statistics to "maximise the size of a medical problem." A survey sponsored by the association found that "one-third of women believe that vaginal odor is normal, and approximately 24% believe that it's normal to experience vaginal itching."<sup>2</sup> This is offered as evidence of women's "lack of knowledge" about vaginal health. The association's website encourages women to contact a healthcare provider when they experience such symptoms.

In fact, good evidence from the primary literature says that both odour and itching occur in women without vaginal complaints.<sup>3,4</sup> The idea that vaginal complaints are due to infectious agents has been heavily promoted by 3M through the association and is implicit in the very naming of its website, which refers to vaginal infections. Yet we know that many women with vaginal complaints do not have an identifiable infectious pathogen.<sup>5</sup>

It is time for clinicians to rethink the almost reflexive response, encouraged by the pharmaceutical industry and its front groups, of reaching for the prescription pad when a patient presents with vaginal complaints. As Yogi Berra also said: "You can observe a lot just by watching."

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### Will industry's latest moves promote public health or private profit?

EDITOR—The issues raised by Moynihan et al are borne out by research conducted by the Consumers' Association.<sup>1,2</sup> We found many examples of pharmaceutical companies forming alliances with patient organisations in order to get their marketing messages out to a wider public under the guise of providing patients with much

needed information. There is now a lot of pressure to allow drug companies to reach the public direct.

This raises some interesting and important questions. For example, why would pharmaceutical companies continue to fund patient organisations when they can communicate with patients direct? How will this affect what the patient organisations can do and the people who rely on their information and support? Will it increase the use of the internet for the purchase of drugs that doctors are not willing to prescribe, and what will the safeguards and regulation be to protect consumers from poor medical advice through this route? Perhaps the most important question of all is why proposals are currently before the European Parliament to reduce regulation of the pharmaceutical industry and to enable direct to consumer advertising of prescription medicines.

All the available evidence shows that this will bring about far reaching and extremely negative consequences for public health throughout the European Community in order to satisfy commercial interests.

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- 2 Consumers' Association. *Promotion of prescription drugs: public health or private profit?* London: CA, 2001. (Policy report.)

### Psychiatry should not accept so much commercial sponsorship

EDITOR—Moynihan et al mention social phobia as one example of the manipulation of medical knowledge by the pharmaceutical industry,<sup>1</sup> but, as Double says, this process is endemic in psychiatry.<sup>2</sup> Since the 1950s drug treatments have dominated psychiatric practice and set the agenda for most psychiatric research, even though it remains difficult to show that long term outcomes are any different from those 100 years ago.<sup>3</sup>

The influence of the pharmaceutical industry is particularly pernicious in psychiatry, where the possibilities for colonising ever more aspects of life are potentially limitless. In psychiatry different paradigms and approaches to treatment are hotly contested. The financial muscle of the pharmaceutical industry has helped to favour a predominantly biological view of psychiatric disorder. This has submerged alternative therapeutic approaches, even though user led research indicates that service users find a wide variety of non-medical approaches valuable in coping with emotional distress.<sup>4</sup>

It is time to uncouple the alliance between psychiatry and the pharmaceutical industry. Users of psychiatric services are profoundly suspicious of this alliance and last year organised a demonstration against sponsorship of the Royal College of Psychiatrists' conference.<sup>5</sup> Members of the Critical Psychiatry Network supported this demonstration.

In the interest of education and science, the medical colleges must be seen to be independent from the commercial interests of the pharmaceutical industry; there has to be absolute transparency concerning the relation between the colleges and the industry. In February this year we wrote to the president of the Royal College of Psychiatrists requesting information about the extent of drug company sponsorship. We await a reply.

The Critical Psychiatry Network argues that the Royal College of Psychiatrists must decline commercial sponsorship for all educational activities, including its annual conference. These steps are necessary to distance the profession from the industry and improve its credibility with service users and the public. We shall be campaigning actively to achieve this.

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### Authors' reply

EDITOR—We welcome the comments and criticisms of our paper, seeing them as part of what we hope will be an ongoing and growing debate about disease mongering. Many of the experiences and views described in the correspondence confirm or expand our concerns about these issues.

We note the acknowledgement by Tiner from the Association of the British Pharmaceutical Industry that "the pharmaceutical industry, with others, is involved in sponsoring the definition of diseases" and welcome his wider reactions to the *BMJ's* theme issue on medicalisation. Similarly we are pleased to receive feedback from the National Osteoporosis Society but reject assertions that our article was unbalanced or poorly researched.

In response to Jacobs, we agree that pharmaceutical treatments can offer great help to those who genuinely suffer from disorders, including social phobia. However, as he rightly points out, we recommend a preference for independently funded information about both disorders and treatments.

In response to Sambrook and Stenmark's letter from Osteoporosis Australia, we acknowledge a mistake in relation to the way our article reported on the recommendations for the one minute risk test for osteoporosis. However, regarding the sources of funding for Osteoporosis Aus-

tralia, the organisation's website ([www.osteoporosis.org.au](http://www.osteoporosis.org.au)) mentions four sponsors, Aventis (a pharmaceutical company that markets the drug risedronate), the Australian Dairy Corporation, Kraft Singles (a popular brand of sliced processed cheese), and Caltrate (a brand of calcium supplement marketed by Wyeth Australia). In other words, while Osteoporosis Australia may indeed receive funding from governments, its site lists commercial sponsors that have a vested interest in some of the activities of Osteoporosis Australia and also appears to be promoting some of the sponsors' products.

We agree that the evidence for the efficacy of exercise is not as strong as for some drug interventions, as Sambrook and Stenmark assert. However, systematic reviews of randomised trials have shown an attenuation of the decline in bone mineral density with exercise,<sup>1,2</sup> and a systematic review found that some forms of supervised exercise reduce the incidence of falls.<sup>3</sup> Observational studies have shown a protective association between regular exercise and hip fracture.<sup>4</sup> The website of Osteoporosis Australia recommends exercise for the "prevention of osteoporosis."

Sambrook and Stenmark attempt to discredit our article by describing evidence based on "conversations with industry insiders" and "personal communications" as "hearsay." Several of the "personal communications" to which they refer were interviews with pharmaceutical company representatives to check facts and include company arguments and perspectives. The "conversations with industry insiders" and other confidential interview material were referred to in our article because of their direct relevance. As these authors may or may not know, public relations experts active in corporate funded disease awareness campaigns are often liable to be far more candid in confidential interviews than in public "on the record" statements.

Sambrook and Stenmark claim that bone densitometry "is widely accepted as the best predictor of future fracture risk." We are not sure what this statement means, but the performance of the test is poor. In a review of bone mineral density measurement the British Columbia Office of Health Technology Assessment summarised published data from five independent evaluations of the predictive performance of bone density measurements.<sup>5</sup> Depending on the threshold values used and the assumed lifetime incidence of hip fracture, studies reported predictive values for positive results in bone mineral density tests ranging from 8% to 36%. This report also emphasised that women of menopausal age are most commonly referred for testing. The majority of these women are at low risk of osteoporotic fracture within the next few years. If the test leads to unnecessary treatment and anxiety (typical effects of disease mongering), it may do more harm than good. We do not seek to downplay the real suffering caused by osteoporotic fractures,

and welcome the increasing emphasis on various forms of prevention and effective treatments of those at high risk, particularly elderly people.

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## Brain drain and health professionals

### Is state ownership of health professionals' intellect being proposed?

EDITOR—In their editorial on the migration of medical professionals Pang et al suggest that "Just as intellectual property rights need to be discussed by developed and developing countries together, so also should the preservation of the intellectual property of a nation, embodied in its health professionals, be addressed by international organisations."

Does this mean that the state or some international organisation has a financial claim on a person's intellect? It is one thing to require public service in exchange for education as long as both parties agree beforehand. It is quite another to extort service or money from people who have paid for their own education; this type of action would be justified only at a time of national calamity, such as a world war.

Because we so value liberty, most Americans would find this view utterly preposterous. Hopefully many British people will as well.

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### Brain drain disseminates skill and advances science

EDITOR—I cannot understand why some people have difficulty understanding the freedom of movement of professionals.<sup>1</sup>

Professionals move from one region to another and from one country to another all the time. It happens everywhere.

This phenomenon is nothing new. The people who leave their country have their reasons for going. Einstein left Germany for the United States in the 1930s for fear of Nazi persecution. Osler emigrated from Canada to John Hopkins University in the United States and eventually ended up in Oxford, England. In the United States we have a variety of professionals from all over the earth. This phenomenon enriches cultures, disseminates skill and information, and advances science and technology.

I see the phenomenon as equivalent to the free flow of trade. People lament what occurs, but many of my classmates in medical school have already given up medicine as a career and have become businessmen. A few are driving taxis to make ends meet.

I opted to go out and see the world, but that has enabled me to embrace medicine as a career. Had I stayed, God knows what would have become of me. People make their own living. Even in countries such as the United Kingdom a quarter of medical graduates leave the medical profession out of despair.

Unless society improves the living conditions of healthcare professionals, people will continue to leave their professions or simply find a better position.

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### Scientists can promote research relevant to their countries after emigrating

EDITOR—Pang et al's editorial describes how, as a result of the brain drain, countries are left with a reduced workforce to carry out crucial activities.<sup>1</sup> We should see where these specialists go.

The brain drain has both positive and negative aspects. Many specialists who emigrate from low income and middle income countries are attracted by international organisations helping to define world health and development priorities. The World Health Organization, for example, attracts the best health specialists to fulfil its mandate to provide support and guidance to ministries of health from 191 countries. And it should do: it would be hard to imagine the top United Nations body that guides health policies not having the best specialists, or not having specialists from low income and middle income countries with experience of the countries concerned who can argue their case.

Countries lose in one way but may gain in another. In health research, for example, scientists migrating from developing countries can promote research activity in priority areas relevant to their countries, thereby

helping to improve the allocation of health research funding to these areas. Their work can be expected to have repercussions in many low income and middle income countries, including their own. This is part of their commitment to improving health conditions in their countries.

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### Relocation is better term than brain drain

**EDITOR**—Freedom of movement is supposed to be a human right, and the movement of professionals from place to place or country to country is not new.<sup>1</sup> Given the world's sociopolitical-economic make up, why not make use of these professionals? This was the question that I put to a professor at an American university. I was interested in his views on what more could be done to address the problem of the lack of health professionals in Africa. He said that governments there should address the issue of the brain drain and why they couldn't keep the professionals.

I wondered why, given that the conditions that created the brain drain still continue, the countries are not finding a way to use the vast repository of knowledge that these professionals have. Not only do they have knowledge about the countries they come from, but many still have strong ties with those countries. Their knowledge of these countries and their presence in the West put them in an advantageous position. Perhaps we should view this movement not as a brain drain but as a relocation.

Professionals in developed countries have better access to new techniques, drugs, and the latest developments in health and medicine, which may be relevant to a country in Africa. And, being from there, they would be well placed to analyse, assess, or advise on how these could best be used in an African setting and make this knowledge available to their counterparts at home. Yet you rarely hear of any attempts to recruit such people for their knowledge. There are virtually no networks that tap this pool of talent.

Prompted by recent developments in antiretroviral therapy, the controversy over prices, and how the drugs were unavailable to Third World markets, I have been trying to contact professionals from Africa who are working in the United States and the United Kingdom. These drugs have been available for over a decade. Why is it only now that African doctors are being trained in their use? Clearly, the health professionals who would be best placed to advise on such drugs are those with access to them and with experience in using them, and of course they would be African health professionals based abroad.

Rather than the movement of professionals being viewed in a negative light, more effort needs to be made to find ways of using their knowledge.

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### Developed countries must say no to trade in medical staff

**EDITOR**—The call for global solutions to the problem of medical migration is welcome indeed.<sup>1</sup> Through its longstanding health programmes in many developing countries Save the Children is acutely aware of the impact of medical migration and the factors that cause it. One factor not touched on in Pang et al's editorial is the increasing pressure on countries to see health services as a potential source of export earnings in the context of increasing liberalisation of trade in services under the auspices of the World Trade Organization.<sup>2</sup>

The World Bank is the most outspoken proponent of this. In its *Global Economic Prospects 2002* it explores service sectors in which developing countries could make balance of payments gains.<sup>3</sup> It makes the following recommendation: "Health services are another area in which developing countries could become major exporters, either by attracting foreign patients to domestic hospitals and doctors, or by temporarily sending their health personnel abroad."

There may be countries where there is a genuine surplus of medical staff and where an excellent health record justifies seeking balance of payments gains through exporting health services. Cuba is the most obvious example, and the government there has established its own trading agency, Servimed, to cater for foreign patients at home and abroad. But most developing countries are characterised by poor health outcomes and chronic shortages of medical staff. It is irresponsible to suggest that they should become major exporters in the health sector rather than marshalling all available resources to address their own health needs.

A binding international code for governments and multilateral organisations may well be the best way of dealing with brain drain in the long term. In the immediate future, however, the World Bank should desist from promoting medical migration as an economic strategy for developing countries.

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## Cholestatic hepatitis in association with celecoxib

### Classification of drug associated liver dysfunction is questionable

**EDITOR**—We appreciated the report by O'Beirne and Cairns concerning a patient with liver test dysfunction in the setting of treatment with the COX 2 inhibitor celecoxib.<sup>1</sup> We are, however, concerned at their use of "cholestatic hepatitis" as the most appropriate description of the pattern of liver test abnormality observed. The patient they described had a maximal aspartate transaminase concentration of 1650 IU/l (reference range 10-40 IU/l), a maximal alkaline phosphatase concentration of 232 IU/l (25-115 IU/l), and peak total serum bilirubin of 123  $\mu$ mol/l (5-20  $\mu$ mol/l).

In broad terms, two categories of drug associated liver injury are encountered commonly, namely cholestatic and hepatocellular.<sup>2</sup> Cholestatic injury has been defined further as occurring when the peak transaminase concentration is less than eight times the upper limit of normal, and the corresponding ALP is greater than threefold normal, whereas hepatocellular injury has been defined as being present when the peak transaminase concentration is greater than eight times the upper limit of normal and the concomitant alkaline phosphatase concentration is less than threefold normal. A mixed pattern of injury, showing features of both, may also be found.<sup>3</sup> According to these criteria the patient of O'Beirne and Cairns had evidence of hepatocellular injury primarily, rather than a mixed pattern as the term "cholestatic hepatitis" suggests. Liver biopsy might have helped to emphasise this distinction.

The article by Maddrey et al referred to in their report was misquoted: where the term alkaline phosphatase was used, it should have read alanine aminotransferase. In that study only 0.4% and 0.3% respectively of 6376 patients treated with celecoxib had maximal alanine aminotransferase and aspartate transaminase concentrations greater than or equal to three times the upper limit of normal. None of these transaminase elevations was greater than eight times the upper limit of normal, in contrast to that found in the patient of O'Beirne and Cairns (about 41 times upper normal limit).

Therefore, although we disagree with the view that this patient had cholestatic hepatitis on the basis of data quoted, the case does represent the first reported instance of severe hepatocellular liver dysfunction in association with celecoxib treatment.

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Competing interests: None declared.

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### Authors' reply

EDITOR—We thank Smith and Mohammed for their interest in our drug point. They correctly identify the unintentional error in paragraph 6. We agree that according to the classification system they quote our case would qualify as a hepatocellular rather than a cholestatic reaction. But this system is outdated.

Despite the publication of a consensus document on classification of drug induced liver disorders in 1990,<sup>1</sup> disagreement still persists about the nomenclature of drug induced liver injury. This issue was discussed at a joint conference between the American Association for the Study of the Liver and the Food and Drug Administration in February 2001.<sup>2</sup>

Cholestatic hepatitis cannot be diagnosed firmly without performing a liver biopsy. It is, however, not our practice to perform a liver biopsy on patients with rapidly normalising abnormalities after a liver function test. We used the term cholestatic hepatitis as we were impressed by the severe symptoms of cholestasis displayed by the patient in our report—namely, jaundice, dark urine, pruritus, and biochemical hepatitis.

Three reports can be found in the literature of similar reactions to COX 2 inhibitors, two of these biopsy proven to be cholestatic hepatitis.<sup>3-5</sup> We therefore remain comfortable with our use of the term cholestatic hepatitis to describe the liver test abnormalities shown in our report.

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### BMA president clarifies his message

EDITOR—Linda Beecham's summary of my inaugural speech as president of the BMA (13 July, p 66) is efficient and fair.<sup>1</sup> It does,

however, contain one minor but important misrepresentation.

I did not describe a third of NHS care as "similar to medicine in the third world." My precise and carefully chosen words were: "Looking at the lowest third of NHS performance, we are, in terms of availability, verging on third world medicine, in what is one of the most affluent countries in the world." The key words were "availability" and "verging." I also said, "broadly, two thirds of NHS medicine is very good, or reasonably good," and my major concern was for the very many patients who cannot get access to that care without lengthy and (to me) unacceptable delays.

The separate issue of whether a president of the BMA should express such personal concerns is, I accept, a valid matter for debate.

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### Post-traumatic psychological distress may present in rheumatology clinics

EDITOR—In their Lesson of the Week Gabriel and Neal mentioned that somatisation of mental disharmony may obscure the diagnosis.<sup>1</sup> Their report concentrated on post-traumatic stress disorder in military personnel, but other groups may have experienced horrific experiences causing spinal pain that results in referral to rheumatologists.

We have reviewed clinic letters of patients seen between June 2001 and February 2002 in a rheumatology clinic specialising in spinal pain. Three new patients referred with spinal pain had clear evidence of post-traumatic psychological distress.<sup>2-4</sup>

**Case 1**—A 25 year old Iraqi student was referred with a history of torture. He had been beaten by the police all over his body, including the spine, on several occasions. He was afraid to go to sleep because of dreams that someone would come for him and take him away. He wakes up screaming, dreaming of his torture.

**Case 2**—A 39 year old Afghanistani woman who was referred told how the Taliban had imprisoned her and her husband; she described being beaten with cables across the back and the feet. She was tearful and described crying out for no apparent reason, saying, "I can't help it; I can't control it." She then said, "I try not to sleep. If I sleep I have bad dreams."

**Case 3**—A 57 year old white woman had walked to her flat three years previously and been assaulted from behind when her handbag was stolen. She was thrown down steps outside her flat and had never entered it since, staying with her son. She now never leaves her home unaccompanied.

We find it concerning that the trauma was noted for only one of the referrals; that waiting times to be seen by the Medical Foundation for the Care of Victims of Torture now exceed one year; and that Harrow psychological services are not resourced to meet these needs. As the physical aspects of care are unlikely to resolve until the psychological issues are addressed, areas where torture victims live need adequate psychological services. Case 3 exemplifies the issues raised by relatively minor physical trauma resulting in emotional distress and major behavioural change, as has been noted after road traffic incidents.<sup>5</sup>

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### Adults still account for many deaths from chickenpox

EDITOR—It was good to learn from Brisson et al's letter that the trend of an increasing number of deaths from chickenpox has reversed in the three years since colleagues and I completed our survey.<sup>1,2</sup> However, Brisson et al disagree with our claim that deaths in adults are rising and state that this is misleading.<sup>1</sup>

Our conclusion that adult deaths had risen was based on statistics covering a period of 31 years (1967-97). Among certified deaths from chickenpox adults accounted for 48% in 1967-77 (88 deaths in 11 years), 64% in 1978-85 (120 deaths in eight years),<sup>3</sup> and 81% in 1986-97 (269 deaths in 12 years).

The contention that our data are misleading on the basis of three further years of data compared with our span of 31 years clearly needs to be placed in context. Moreover, there is a precedent for periods of lower mortality, as discussed below for the period 1989-91. The main body of our paper stated that deaths from chickenpox in adults have increased in number and proportion. We inadvertently used the present tense in the abstract and cannot claim to see into the future.

We looked at deaths noted by the Office for National Statistics for the 13 years 1985-97 (table). This table, which was not published in our paper for reasons of space, shows that, except in two years, the annual number of deaths was fairly consistent. The exceptions were 1989 and 1996, when the case fatality rates based on consultation rates from the Royal College of General Practi-

Numbers of certified deaths from chickenpox and estimated case fatality rates in England and Wales, 1985-97

Year	No of RCGP consultations per 100 000	No of ONS certified deaths	No of cases in population*	Case fatality rate per 100 000
1985	544	271 891	25	9.19
1986	556	278 890	25	8.96
1987	514	258 748	24	9.28
1988	621	313 729	30	9.56
1989	699	354 393	19	5.36
1990	552	280 858	24	8.55
1991	554	283 089	24	8.48
1992	653	334 839	27	8.06
1993	643	330 753	30	9.07
1994	623	321 593	23	7.15
1995	484	250 809	22	8.77
1996	597	310 500	39	12.56
1997	486	253 746	20	7.88
Average	579	276 295	26	9.22

RCGP=Royal College of General Practitioners. ONS=Office for National Statistics. \*Based on RCGP consultation rates.

tioners were also exceptional. We have no explanation for this.

The total number of deaths in 1986-8, 1989-91, 1992-4, and 1995-7 were 26, 22, 27, and 27 respectively. This does not show that, as Brisson et al state, "The number of deaths from chickenpox and case fatality rates were significantly higher in 1995-7 [the period of our study] than at any other period." The overall case fatality rates in the table do not show this either.

The main messages of our paper are that mortality from chickenpox is not negligible; adults account for a high proportion of deaths; and the number and proportion of adult deaths increased substantially between 1967 and 1997.

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## Evaluation of treatments is threatened by EC directive

EDITOR—Singer and Müllner draw attention to how the European Directive 2001/20/EC might stop trials of treatments for patients rendered suddenly mentally incapacitated by, for example, cardiac arrest, head injury, stroke, or status epilepticus.<sup>1</sup> Many of these patients are in no position to give the consent that the directive demands for entry into a clinical trial. Furthermore, they may well not have a legally acceptable representative immediately available to give proxy consent in situations where any delay in starting treatment might be disastrous.

Sadly, in Scotland such trials may already be impossible. The Adults with Incapacity (Scotland) Act, 2000 requires consent from the adult's proxy or next of kin; this is despite numerous attempts over

four years by medical researchers to explain the consequences of this restriction to the lawyers drafting the bill. The United States's solution to the problem is for a waiver of consent in explicit and well defined circumstances and with appropriate safeguards.<sup>2</sup> This position is also taken by the British ethicist Doyal, who wrote, "To exclude them from participation in research specific to their conditions and treatments might deprive both them and others of potential benefit."<sup>3</sup>

Europeans should wake up to the threat to the evaluation of treatments for millions of future patients. The lawyers and politicians must sort out just whose interest they are protecting when framing European legislation.

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## Rational, cost effective use of investigations

### Rising workload and costs in diagnostic departments must be contained

EDITOR—Winkens and Dinant have highlighted some issues regarding the rising workload in pathology.<sup>1</sup> In 1985 the workload in most diagnostic departments in the United Kingdom was reported to have been rising 10% a year whereas the

number of inpatients and outpatients increased by less than 2% a year<sup>2</sup>; it is roughly similar now. A review of laboratory audits showed that the number of inappropriate tests requested by clinicians varies from 5% to 95%.<sup>3</sup>

The common perception among physicians is that these tests are cheap. Their unit cost may be low, but they have a high cumulative cost.<sup>3</sup> The annual bill for operating laboratory tests is greater than the annual cost of operating computed tomographic scanners.<sup>3</sup>

Several methods to modify clinicians' use of diagnostic tests have been reported. The most potent interventions are methods that facilitate the preferred behaviour through blocking inappropriate requests or defaulting to the intended practice.<sup>4</sup> In a study in the United States several characteristics were associated with a low level of laboratory use: being a leader; being part of a service group whose leader was a low user, clinical experience, being board certified, and being a graduate from "established" medical schools in the north east of America, Chicago, or California.<sup>5</sup>

The two most important reasons for the rising workload and costs in laboratories is the ease with which tests can be requested and lack of ownership by clinicians, as the problem is viewed largely as a laboratory problem. Good leadership and medical training are important. Thus consultants should play a key part as leaders, and a course on cost containment should be made compulsory in the medical curriculum.

The concepts of "profile" and "routine" should be abolished and investigations tailored to individual needs. It must be made mandatory for all junior doctors to get a certificate of competence in laboratory use from their consultants based on the information produced by the laboratory.

The question we have to grapple with is how we want to use our resources: whether to have more investigations or to fund more nurses, doctors, or such like to improve patient care. I suspect that the response would be similar to that of those people who say that they would prefer higher taxes to fund public services but vote otherwise in the polling booth. The decision we make will dictate the quality of NHS we have. Let's have more doctors and nurses.

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# Article gave unbalanced view of overuse of diagnostic tests

EDITOR—Winkens and Dinant report that diagnostic tests are overused by medical practitioners, and they propose various measures to curtail this problem.<sup>1</sup> We believe, though, that their view is unbalanced. Investigations should only be done if they have potential therapeutic implications, but patients are entitled to be assessed adequately. Even experts' recommendations on appropriate diagnostic testing may be outdated by the time they are reported.

Patients with rheumatoid arthritis and systemic lupus erythematosus have many more cardiovascular events than other patients.<sup>2,3</sup> These events are a major determinant of the long term morbidity and mortality in these diseases. Abnormal cardiovascular risk profiles in these diseases show traditional risk factors such as dyslipidaemia<sup>2,3</sup> and non-traditional ones such as a raised acute phase response<sup>2</sup> and raised serum homocysteine concentrations.<sup>3</sup>

These risk factors are associated with atherosclerosis in the two diseases.<sup>2,3</sup> Recent guidelines on the evaluation and management of rheumatoid arthritis and lupus, reported by the American College of Rheumatology, do not deal with the issue of cardiovascular disease. We believe that not evaluating cardiovascular risk—both clinically and by laboratory testing—may no longer be appropriate, and we start treatment accordingly in rheumatoid arthritis and lupus.

Similarly, gout is associated with atherosclerosis.<sup>4</sup> Hyperuricaemia is a documented manifestation of the metabolic syndrome or insulin resistance syndrome, while the latter predicts a threefold increase in the incidence of cardiovascular events.<sup>4</sup> Most patients with gout have dyslipidaemia among other treatable cardiovascular risk factors.<sup>4,5</sup> Snaith recently commented: "There is much work to be done before writing a prescription for allopurinol."<sup>5</sup>

Because of the costs involved in treating cardiovascular disease, we think that the assessment and treatment of cardiovascular risk factors in rheumatoid arthritis, lupus, and gout is cost effective, at least in the long term.

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# Primary care organisations must take charge of laboratory expenditure

EDITOR—Winkens and Dinant offer a gloomy but realistic assessment of the many attempts to change doctors' behaviour related to laboratory testing.<sup>1</sup> The experience documented is similar in many respects to that in New Zealand. In one area here, however, comprehensive sustained strategies achieved an appreciable reduction in laboratory expenditure, and this has been maintained over several years.

Pegasus Health in Christchurch is a primary care organisation similar in many respects to the primary care groups and trusts in England. It has a membership now of 230 general practitioners with a global budget of around NZ\$80m (£25m; US\$39m; €38m), and it established a comprehensive laboratory budget holding programme in 1994. This was through a contract with the then funding authority, which enabled it to keep nearly all savings.

An evaluation after one year showed that savings of 23% had been achieved and that the pronounced variation between groups with high and low costs per consultation had been greatly reduced.<sup>2,3</sup> The study conclusively showed that general practitioners, within the incentive of a defined budget and the ability to use savings for improving patient services, were able to make major savings with no evidence of any reduction in the quality of care.

A subsequent study in Pegasus showed that savings were being maintained but that variation was still inappropriately high.<sup>4</sup> There was some evidence that better quality care was associated with lower expenditure. Since then per capita expenditure on laboratory services has been maintained at between NZ\$20 (£6.20) and NZ\$25 (£7.75), whereas the national cost weighted figure per capita has risen to NZ\$37 (£11.46).

Primary care organisations have generally sought to engage in budget holding of laboratory services, but this has been inhibited by a confused and conflicting contracting process between funders and primary care organisations. There have been disagreements about setting budgets and what levels of savings could be retained by the primary care organisation. The experience is a prime example of the inability of bureaucrats to collaborate effectively and constructively with professional aspirations. It is the main reason behind the failure to extend the successful experience of Pegasus to a wider constituency.

Much more constructive action will now be needed as the new population funded district health boards begin to grapple with reducing their wide underfunding and overfunding on laboratory and related services. Having laboratory budgets held by primary care organisations along the Pegasus model seems to be the only answer.

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# Bravo, brave *BMJ*, for the rapid response section

EDITOR—As a subspecialist who formerly rarely read a generalist journal, I am a total convert to the *BMJ*, this treasury of free thinking and repartee. The rapid response section not only leads to a democratisation of science and medicine (formerly we were prevented from free participation by the whims of editors), but unpublished ideas can be circularised, and this can lead to research and changes.<sup>1</sup> Imagine Leonardo da Vinci in today's research climate without a research grant. Many of his ideas would have been ridiculed as preposterous.

I think a section of "New Ideas" needs discussion, and even a place where that negative result or study that has never seen the light of day can be mentioned. I with other colleagues spent several years on a large prospective study of ploidy in lung cancer, which refuted an inferior positive study we had published in the *Lancet*. Not surprisingly, this far more technically advanced second study, with negative results, was never accepted for publication. Everyone had lost interest, and the erroneous conclusions of the first paper stand in perpetuity as a reminder of the stupidity of medical publishing fashions. It remains in my filing cabinet to this day.

As no counterpart to rapid responses exists in unenlightened Australia (the land of the endless long weekend), it is delightful to share ideas from half a world away instantaneously and to be able to respond early to articles while the Brits are asleep and before the milkman arrives. Other journals should get out of the telegraph-and-morse-code era.

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# Rapid responses

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